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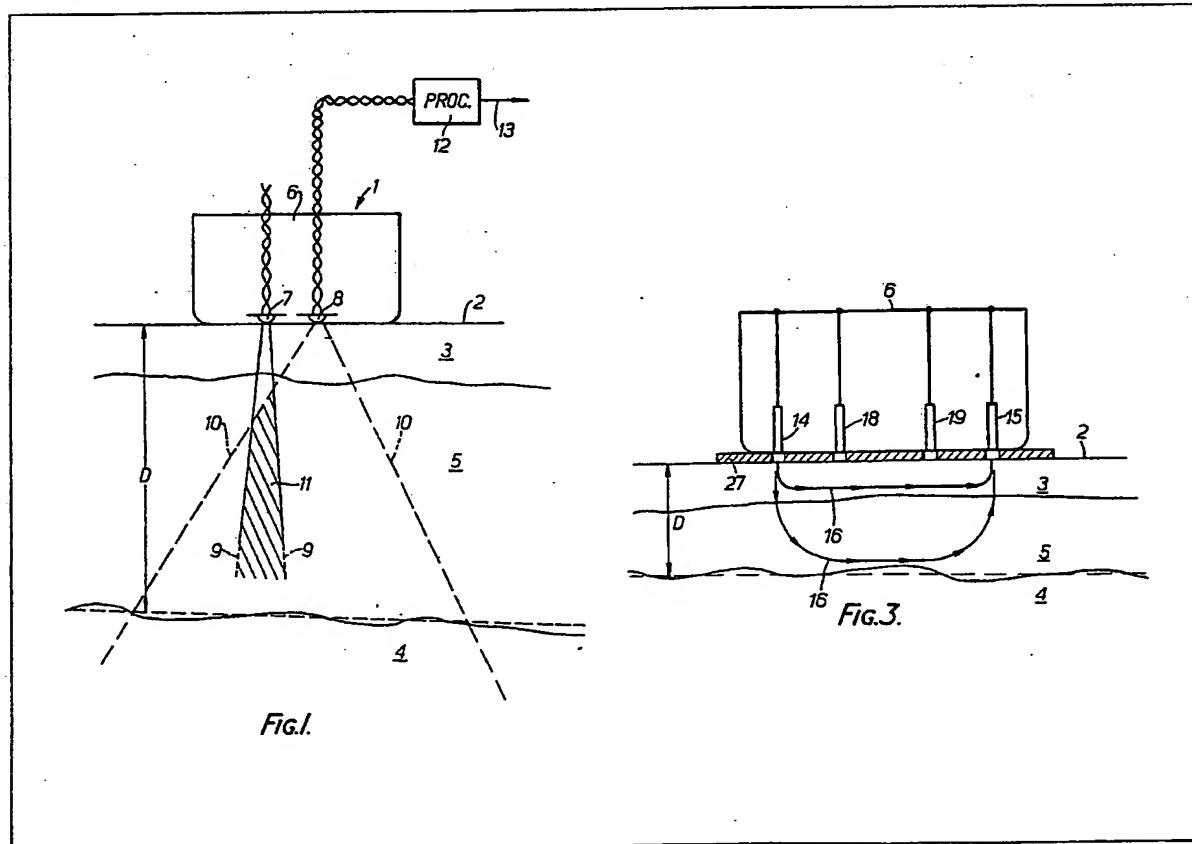
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## (54) Investigating substances in a patient's bloodstream

(57) Investigation of substances such as oxygen, CO<sub>2</sub> or glucose in a patient's bloodstream by passing the substances transcutaneously to a sensor is accompanied by a bloodless assessment of capillary blood flow rate, so that a warning indication 13 may be provided of any reduction in capillary blood flow rate (due to shock or other physiologic conditions), under which reduced

flow condition the detected amount of the substance does not represent the true amount present in arterial blood. Optical measurements, (Figures 1 and 2), or impedance measurements, (Figure 3), are used for the bloodless assessment of capillary blood flow rates. In the former case optical radiation from LED 7 is backscattered and reflected from a region 11 within the patient's body of the capillary bed 5 to detector 8. In the latter case, an alternating electric current is caused to flow between electrodes 14, 15 along a conduction path 16 confined substantially to the depth D of the capillary bed 5 and the voltage drop between these electrodes, or preferably between electrodes 18, 19 is measured.



The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

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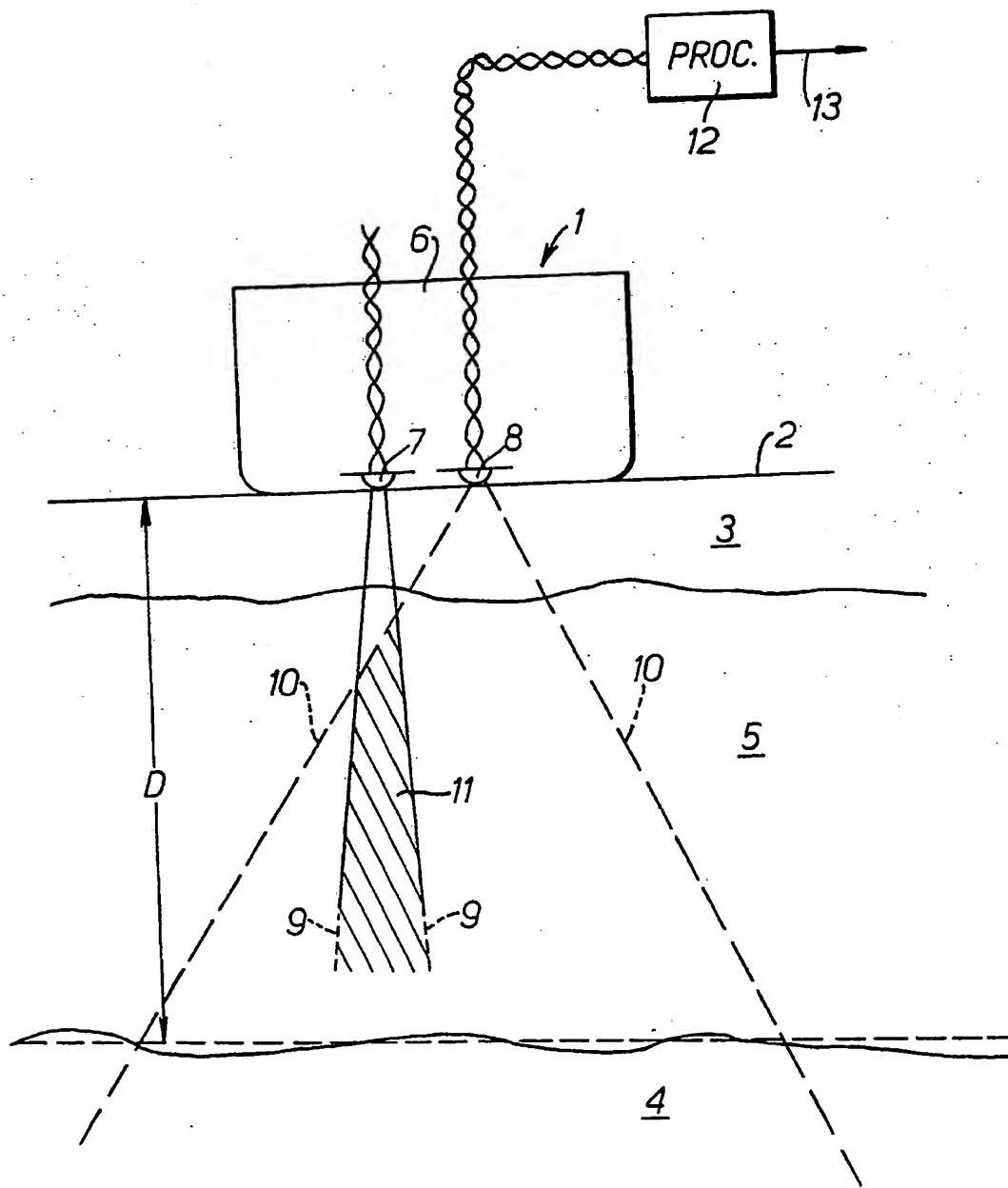


FIG.1

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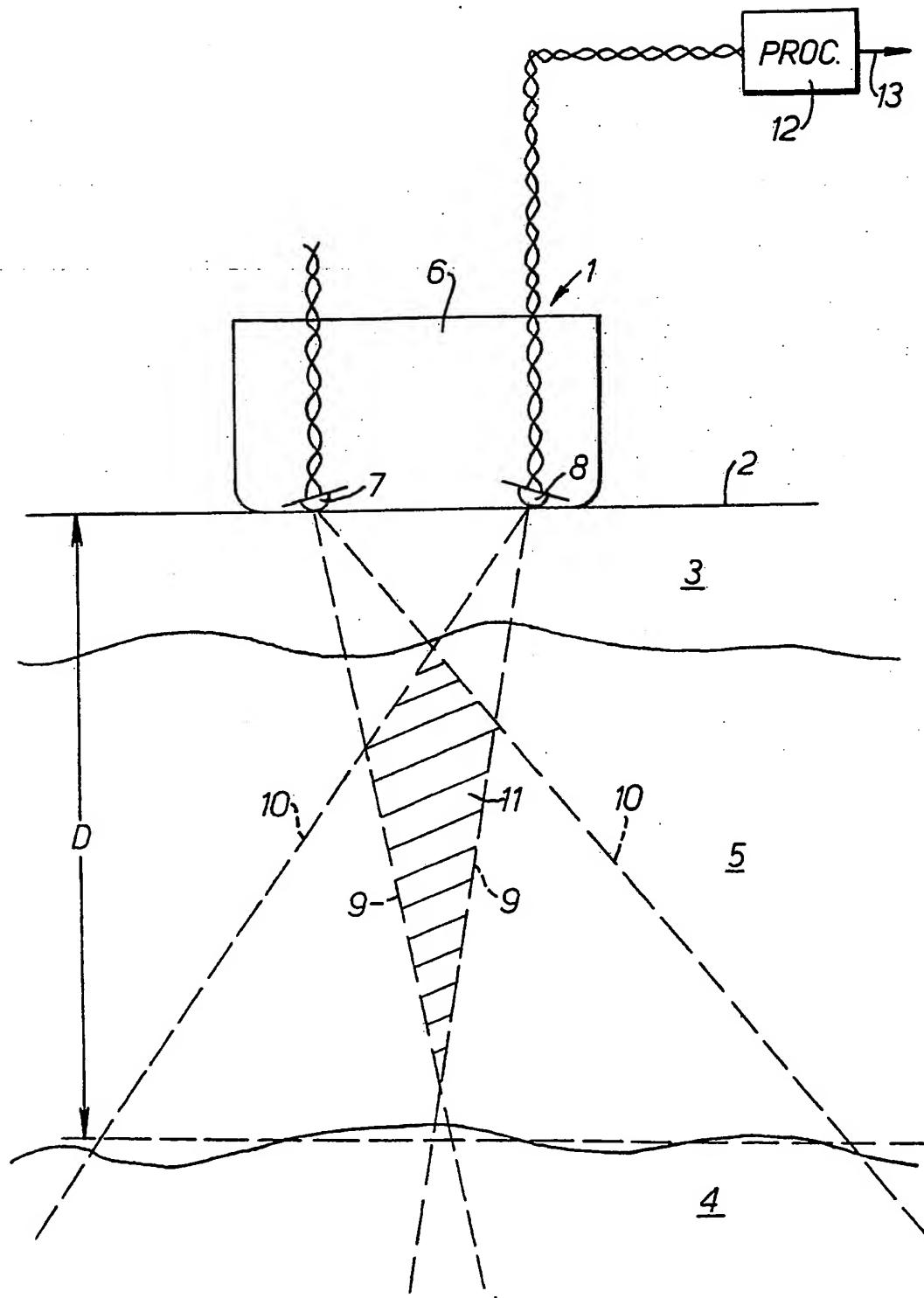
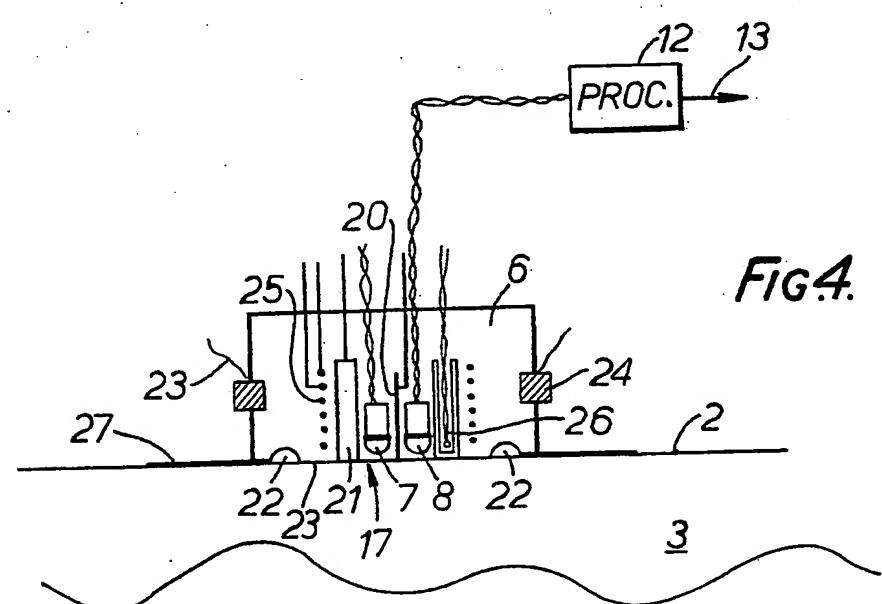
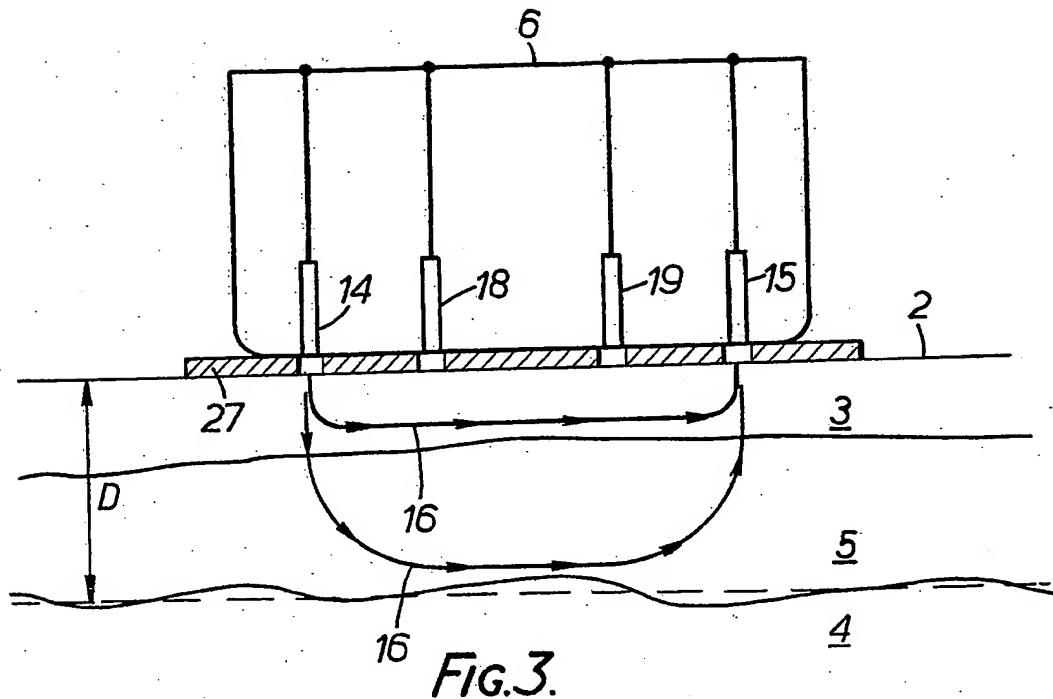


FIG.2.

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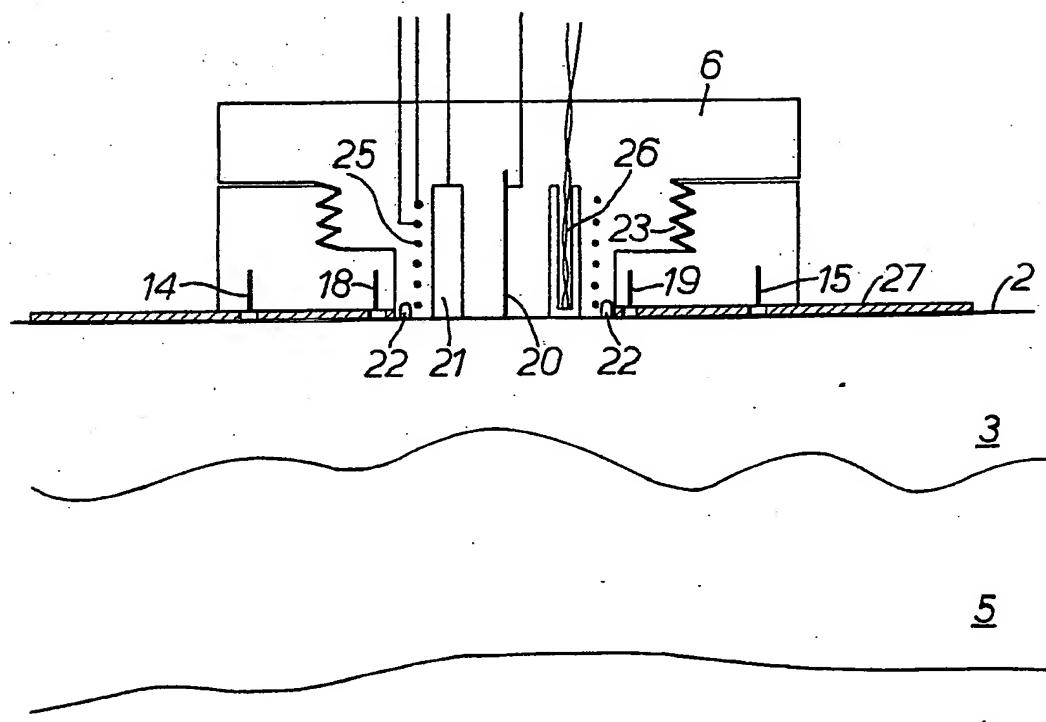


FIG. 5.

## SPECIFICATION

## Investigating substances in a patient's bloodstream

5 The present invention is concerned with investigating substances in a patient's bloodstream which are capable of passing transcutaneously from the capillary blood vessels or loops to the skin surface. In particular, though not exclusively, the invention is 10 concerned with determining gas (such as oxygen or  $\text{CO}_2$ ) partial pressure in blood and also blood flow rates, using in each case a bloodless measuring technique. The invention could, however, be used for measuring glucose concentration for example.

15 For the avoidance of doubt, "patient" is used throughout this specification to mean a human, animal or other creature, whether healthy or ill.

It is known to determine the partial pressure of a gas, e.g. oxygen, in the blood stream of a patient by 20 inserting a catheter through the skin and into an artery to make the necessary measurement. However the use of a catheter can involve risk to the patient's life and in any event will cause discomfort to the patient. To overcome this difficulty, trans- 25 cutaneous gas sensors have been devised which merely have to be held against a body surface of a patient without having to immerse any part of the sensor in blood. These gas sensors utilise the phenomenon that gas in the bloodstream, when 30 carried close to the skin surface by the capillary loops or vessels branching out from the main arteries and contained within a layer (capillary bed) between the arterial region (containing the main arteries) and the skin surface layer (consisting of the 35 epidermis and sub-epidermal region), diffuses through the skin surface layer to the outer surface where a transducer produces a signal related to the partial pressure of the gas in the capillary loops.

In general, it is the partial pressure of the arterial 40 gas which needs to be determined and not that of the blood in the capillary loops. However, it has been found that by locally heating the skin surface using a transcutaneous gas sensor of the thermal stimulation type which includes its own controlled heater 45 for maintaining the local skin temperature at a predetermined, elevated, temperature, the capillary loops open further to receive an increased blood flow such that the capillary loops now contain arterial blood. The resulting measurement made by 50 the transcutaneous gas sensor is then closely equivalent to the partial pressure of the gas in the arterial bloodstream.

It is also known that skin blood flow can be 55 reduced significantly by physiological processes (for example when the patient is under a state of shock) and so the measurement obtained from the skin mounted transcutaneous gas sensor of the thermal stimulation type may not always accurately indicate the arterial value. Additionally, if a reduction in 60 capillary blood flow occurs without detection, damage to the skin surface may result since in removing the cooling effect on the heat produced by the oxygen sensor by the flow of blood through the capillary loops, the skin temperature immediately 65 beneath the gas sensor will rise.

According to the invention from one aspect, there is provided a sensor device to be held against a body surface of a patient for use in investigating substances in the bloodstream, comprising a support

70 body, a transcutaneous sensor of the thermal stimulation type on the support body for determining bloodlessly a property of a substance in a patient's blood stream, and a flow detector device for assessing bloodlessly the blood flow rate in a region of the

75 capillary bed positioned beneath the transcutaneous sensor, the flow detector device comprising radiation emitting means, including radiation directing means mounted on said support body, arranged so as, with the sensor device held against a body

80 surface of the patient, to direct optical radiation into the patient's body along a transmission path extending below said body surface, receiver means, including further radiation directing means mounted on said support body, arranged to detect optical radiation

85 backscattered or reflected within the patient's body from said transmission path along a reception path, the first and second radiation directing means being so arranged that substantially only radiation backscattered or reflected from within a region of the

90 capillary bed below the transcutaneous sensor is detected, and a processor arranged to produce an output indication of the capillary blood flow rate from the detected backscattered or reflected radiation.

95 "Optical" as used herein is intended to cover radiation in the infrared as well as ultraviolet wavebands.

According to the invention from a second aspect there is provided a sensor device to be held against a 100 body surface of a patient for use in investigating substances in the bloodstream, comprising a support body, a transcutaneous sensor of the thermal stimulation type on the support body for determining bloodlessly a property of a substance in a

105 patient's bloodstream, and a flow detector device for assessing bloodlessly the blood flow rate in a region of the capillary bed positioned beneath the transcutaneous sensor, the flow detector device comprising means on the support body for applying alternating

110 current, with the sensor device held against a body surface of the patient, between first and second spaced-apart points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement

115 of the current applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the

120 patient's body to be measured to provide an indication of the capillary blood flow rate.

In both cases the function of the flow detector device is that if the measured capillary flow rate falls below an appropriately selected predetermined 125 value, the indicated property of the substance under investigation in the bloodstream (e.g. gas partial pressure value provided by the gas sensor) would be discarded as unreliable.

The output reading of the flow detector device 130 could be observed by an operator but, preferably,

the sensor device further comprises means arranged to provide an indication if the blood flow rate assessed by the flow detector device falls below a predetermined level. Alternatively or in addition, 5 means can be provided arranged to prevent the effective use of the transcutaneous sensor if the blood flow rate assessed by the flow detector device falls below a predetermined level.

Alternatively, the sensor device may further comprise a visual display device arranged to provide 10 respective displays on the same time base of said property, determined by the transcutaneous sensor, and of the blood flow rate assessed by the flow detector device. This particular method of displaying 15 the measured information is of particular assistance when the apparatus is manned. Usually, the transcutaneous sensor will be a transcutaneous oxygen or CO<sub>2</sub> sensor for determining the partial pressure of oxygen or CO<sub>2</sub> in the bloodstream.

20 The invention is also concerned with novel techniques for measuring capillary blood flow rates:

According to the invention from a third aspect there is provided a flow detector device for use in assessing bloodlessly capillary blood flow rate in a 25 patient, comprising a support body, optical radiation emitting means, including radiation directing means on the support body, arranged so as, with the flow detector device held against the body surface of a patient, to direct optical radiation into the patient's 30 body along a transmission path extending below said body surface, receiver means, including further radiation directing means, mounted on said support body, arranged to detect optical radiation backscattered or reflected within the patient's body from said 35 transmission path along a reception path, the first and second radiation directing means being so arranged that substantially only radiation backscattered or reflected from within a region of the capillary bed below the flow detector device is 40 detected, and a processor arranged to produce an output indication of the capillary blood flow rate from the detected backscattered or reflected radiation.

In one arrangement, the transmission and reception paths overlap only in said region of the capillary bed. Alternatively or in addition, the radiation emitting means is so arranged that the intensity of the transmitted optical radiation is insufficient to penetrate deeper into the patient's body than the depth of 50 the capillary bed. The first and second-mentioned radiation direction means can each comprise an optical focussing device, these focussing devices being respectively associated with an optical source and an optical receiver, both mounted on said 55 support body. Moreover, the first and second-mentioned radiation directing means may each take the form of a fibre-optic waveguide mounted at one end on said support body and optically connected at the other end to an optical source or an optical 60 receiver, as the case may be. Alternatively, the radiation emitting means and receiver means may each include an optically deviating portion which constitutes, at least partly, the first or second-mentioned radiation directing means, as the case 65 may be.

In accordance with a corresponding flow measuring technique for assessing bloodlessly capillary blood flow rate in a patient, optical radiation is directed into the patient's body along a transmission -

70 path extending below a body surface of the patient; substantially only backscattered or reflected radiation from within a region of the capillary bed on said transmission path is detected after propagating from said region along a reception path, and an output 75 indication is produced of the capillary blood flow rate from the detected radiation.

According to the invention from a fourth aspect, there is provided a flow detector device for use in assessing bloodlessly capillary blood flow rate in a 80 patient, comprising a support body, means on the support body for applying alternating current, with the flow detector device held against a body surface of the patient, between first and second spaced-apart points on the patient's body so that current will 85 flow along a path within the patient's body extending between said points, the arrangement of the current applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body 90 for enabling the voltage drop along at least part of the length of the current path within the patient's body to be measured to provide an indication of the capillary blood flow rate.

The current applying means and the voltage drop 95 measuring means can together be constituted by first and second spaced-apart electrodes across which alternating current may be applied and the voltage drop measured. In a preferred arrangement, however, the current applying means comprises first 100 and second spaced-apart electrodes and the voltage drop measuring means comprises third and fourth electrodes which are both arranged between the first and second electrodes and have a mutual separation.

105 In accordance with a further method of assessing bloodlessly capillary blood flow rate in a patient, alternating current is applied between two spaced-apart points on a body surface of the patient so as to cause current to flow along a path within the 110 patient's body extending between said points and confined substantially to the depth of the capillary bed, and the voltage drop along at least a part of the length of said path is measured to provide an indication of the capillary blood flow rate.

115 For a better understanding of the invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

*Figure 1* diagrammatically illustrates a first form of 120 optical flow detector device,

*Figure 2* shows a modification,

*Figure 3* shows an "impedance type" flow measuring device,

*Figure 4* shows a sensor device including a 125 transcutaneous gas sensor and a flow detector device similar to that shown in *Figure 1*, and

*Figure 5* shows a similar sensor device but adopting a flow detector device corresponding to that shown in *Figure 3*.

130 Referring to *Figures 1 and 2*, a flow detector device

1 is shown held in position against a body surface 2 of a patient. Reference 3 represents the skin surface layer, reference 4 represents the arterial region of the patient's body where the main arteries of the 5 patient's bloodstream are situated, and capillary loops or vessels which lead blood from the main arteries close to the skin surface and then return the blood back to the main venous blood stream are contained within the capillary bed 5 which is a layer 10 disposed between the skin surface layer 3 and arterial region 4.

The flow measuring device 1 comprises essentially a support body 6 which is formed in its underside surface, which rests on the body surface 2, with two 15 cavities in which are located, respectively, a directional optical source 7 (e.g. a semiconductor light source) and directional optical receiver 8 (e.g. semiconductor light sensor) which are provided with respective sets of electrical connection leads, as 20 shown. Optical radiation is directed from the optical source 7, for example by means of a reflective part incorporated in the source, downwardly into the patient's body and passes along a transmission path.

25 In practice the lateral boundaries of the transmission path are not very clearly defined but in Figures 1 and 2 they are very schematically represented by the straight lines 9, for ease of understanding. As the radiation propagates along the transmission path, it 30 is being backscattered and reflected. The receiver 8 which can be given directivity by a collecting reflective part for example, detects backscattered and reflected radiation passing along a reception path having lateral boundaries, again represented 35 very diagrammatically at 10. The shaded area 11 represents the region of overlap between the transmission and reception paths. Clearly, the receiver 8 will respond substantially only to backscattered energy from the shaded area 11. It is of especial 40 importance to notice that in both Figures 1 and 2 the shaded area is confined to within the capillary bed. This is fulfilled in Figure 1 by adjusting the intensity of the transmitted optical radiation such that it is unable to penetrate lower than the depth D of the 45 capillary bed. In Figure 2, on the other hand, a source of much brighter intensity is used, but the directivity of the two optical paths is such that the region 11 is confined substantially to the capillary bed. Of course it is possible to adopt both measures to achieve the 50 required positioning of the region 11. Another possible measure which could be used alone or in addition is to use separate focussing devices in conjunction with the optical source and receiver respectively.

55 The output signal produced by the receiver 8 then passes via its electrical connection leads to a processor 12. The degree of backscatter and reflection from within the region 11 is related to the volume of blood in the region 11. Therefore, electronic processing by 60 the processor 12 of the output signals from the receiver 8 provides an indication at 13 of capillary blood flow changes.

In a modification, the optical source and receiver can be separate from the support body, there then 65 being respective fibre-optic waveguides optically

connected at one end in each case to the optical source or receiver and mounted at the other end on the support body so as to terminate at the underside of the support body.

70 Another embodiment is shown in Figure 3. In this embodiment the flow detector device 1 is held in position by double-sided sticky tape 27 applied between the undersurface of the support body 6 and the body surface 2. Embedded in the support body, 75 which consists of electrically insulative material, are two electrodes 14, 15 with respective connection leads shown very diagrammatically in Figure 3. Holes are provided in the sticky tape in register with the electrodes 14, 15 and these holes are filled with 80 an electrically conductive gel. In this way, the electrodes are maintained in electrically conductive connection with the body surface 2, so that alternating current of constant amplitude applied to these electrodes will cause a current to flow between the 85 electrodes along a current carrying path within the patient's body. The boundaries of the current flow path (again shown very schematically - at 16 - but being in practice less well-defined than actually indicated) are confined substantially to the skin.

90 surface layer 3 and capillary bed 5 but do not extend into the arterial region 4. In other words, the current carrying path is confined substantially to the depth of the capillary bed. Two further electrodes 18, 19 arranged in the same manner in the support body 6 95 as the electrodes 14, 15 are positioned between the electrodes 14, 15 and are mutually separated from one another.

The current passing through the body between the electrodes 14, 15 causes a voltage drop to be 100 established across the electrodes 18, 19. The amplitude of this voltage is related to the electrical impedance of the tissue beneath the flow detector device, and this is strongly influenced by the relative proportions of highly conductive blood and poorly 105 conductive skin and tissue. Furthermore, it can be demonstrated that the impedances presented by the different electrode/gel/body surface connections can be taken to be largely self-cancelling, so far as having any effect on the voltage drop is concerned.

110 Also, it can be assumed that the voltage drop produced by the current flowing through the skin surface layer 3 is independent of blood flow changes in the capillary loops. Thus the amplitude of the voltage provides a relatively reliable indication of the 115 capillary blood flow rate.

In a simplified embodiment, only two electrodes are provided embedded in the support body. Alternating current of constant amplitude is applied between these electrodes and the voltage drop 120 across the electrodes measured to give an indication of the capillary blood flow rate. However, although simpler this embodiment is less advantageous because the impedances existing at the different electrode/gel/body surface connections introduce 125 inaccuracies.

It must be stressed that the described flow detector devices merely give an assessment of blood flow rate changes, i.e. they give qualitative rather than quantitative results. Nevertheless, such indications 130 can, for certain purposes, be very useful, particularly

in the application now to be described to certain transcutaneous measurements.

Referring now to Figure 4, there is shown a sensor device for investigating partial pressure of gas (usually oxygen or CO<sub>2</sub>) in blood which incorporates a transcutaneous oxygen or CO<sub>2</sub> sensor 17 mounted on the support body 6, the sensor 17 consisting in the case of the sensor device shown of an electrochemical oxygen cell comprising a cathode 20, anode 21, and a reservoir 22 containing electrolyte trapped behind a membrane 23 which is stretched around the side of the support body and secured to the side walls thereof by means of a sealing ring 24 extending around the side walls of the support body.

6. The transcutaneous sensor 17 also consists of an electrical heating coil 25 controlled by a thermistor 26 so as to raise and maintain the skin surface temperature immediately beneath the electrochemical cell at a predetermined temperature, typically 20 43°C. Under such conditions of thermal stimulation, the blood flow from the arteries into the capillary loops or vessels is increased and oxygen concentration in the capillary loops becomes very similar to that actually existing in the main arteries. Therefore, 25 the output reading determined from the electrochemical cell represents the true arterial gas partial pressure.

Also mounted on the support body 6 is a flow detector device 1 of essentially identical construction 30 to that shown in Figure 1 (although it could alternatively be of the modified arrangement shown in Figure 2). The output indication 13 provided by the processor 12 serves as a warning when the capillary flow rate falls below a predetermined level, which 35 would be arbitrarily chosen such that the reading given by the electrochemical cell of gas partial pressure would differ from the reading under normal, thermally stimulated, flow conditions sufficiently that the reading would be regarded as one which 40 should be discarded. The signal 13 could be used to provide a visual and/or audible warning such that an operator would then discard the output data from the electrochemical cell as long as the warning is present. In one preferred arrangement, the outputs 45 from the electrochemical cell and flow detecting device can be presented simultaneously on a visual display device with the two sets of data arranged on the same time base. For example, the display device could be a dual pen recorder. Then, the tracings on 50 the recording sheet could be observed periodically and the parts of the gas partial pressure data which are to be discarded would be readily apparent at a glance from the detected capillary blood flow rate tracing. In another preferred arrangement, a suitable 55 control circuit could be used automatically to render the electrochemical cell ineffective in the event of the flow detector device indicating that the capillary blood flow rate has fallen below the predetermined level indicative of normal flow under thermally 60 stimulated conditions.

Figure 5 is another embodiment which constructionally is very similar to that shown in Figure 4 except that the membrane 23 is trapped between two screw together parts, together constituting the 65 support body, and the flow detector device is

replaced by a flow detector device of the construction shown in Figure 3, there being a large central hole cut in the sticky tape 27 to allow the membrane 23 to be positioned so as to be contacted by gas 70 which has passed transcutaneous to the skin surface 2. The operation of the sensor device shown in Figure 5 corresponds exactly to that of Figure 4, and therefore will not be described in any further detail.

## 75 CLAIMS

1. A flow detector device for use in assessing bloodlessly capillary blood flow rate in a patient, comprising a support body, optical radiation emitting means, including radiation directing means on the support body, arranged so as, with the flow detector device held against the body surface of a patient, to direct optical radiation into the patient's body along a transmission path extending below said body surface, receiver means, including further radiation directing means mounted on said support body, arranged to detect optical radiation backscattered or reflected within the patient's body from said transmission path along a reception path, the first 90 and second radiation directing means being so arranged that substantially only radiation backscattered or reflected from within a region of the capillary bed below the flow detector device is detected, and a processor arranged to produce an output indication of the capillary blood flow rate from the detected backscattered or reflected radiation.
2. A flow detector device according to claim 1, wherein the transmission and reception paths overlap only in said region of the capillary bed.
3. A flow detector device according to claim 1 or 2, wherein the radiation emitting means is so arranged that the intensity of the transmitted optical radiation is insufficient to penetrate deeper into the 105 patient's body than the depth of the capillary bed.
4. A flow detector device according to any preceding claim, wherein the first and second-mentioned radiation directing means each comprise an optical focussing device, these focussing devices 110 being respectively associated with an optical source and an optical receiver, both mounted on said support body.
5. A flow detector device according to any preceding claim, wherein the first and second-mentioned radiation directing means each take the 115 form of a fibre-optic waveguide mounted at one end on said support body and optically connected at the other end to an optical source or an optical receiver, as the case may be.
6. A flow detector device according to any one of claims 1 to 4, wherein the radiation emitting means and receiver means each include an optically deviating portion which constitutes, at least partly, the first or second-mentioned radiation directing means, as 125 the case may be.
7. A flow measuring device substantially as hereinbefore described with reference to Figure 1 or Figure 2 of the accompanying drawings.
8. A method of assessing bloodlessly capillary 130 blood flow rate in a patient, in which optical

radiation is directed into the patient's body along a transmission path extending below a body surface of the patient, substantially only backscattered or reflected radiation from within a region of the 5 capillary bed on said transmission path is detected after propagation from said region along a reception path, and an output indication is produced of the capillary blood flow rate from the detected radiation.

9. A flow detector device for use in assessing 10 bloodlessly capillary blood flow rate in a patient, comprising a support body, means on the support body for applying alternating current, with the flow detector device held against a body surface of the patient, between first and second spaced-apart 15 points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement of the current applying means being such that the current carrying path is confined substantially to the depth of the 20 capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the patient's body to be measured to provide an indication of the capillary blood flow rate.

25 10. A flow detector device according to claim 9, wherein the current applying means and the voltage drop measuring means are together constituted by first and second spaced-apart electrodes across which alternating current may be applied and the 30 voltage drop measured.

11. A flow measuring device according to claim 9, wherein the current applying means comprises first and second spaced apart electrodes and the voltage drop measuring means comprises third and 35 fourth electrodes which are both arranged between the first and second electrodes and have a mutual separation.

12. A flow measuring device substantially as hereinbefore described with reference to Figure 3 of 40 the accompanying drawings.

13. A method of assessing bloodlessly capillary 45 blood flow rate in a patient, wherein alternating current is applied between two spaced-apart points on a body surface of the patient so as to cause current to flow along a path within the patient's body extending between said points and confined substantially to the depth of the capillary bed, and the voltage drop along at least a part of the length of 50 said path is measured to provide an indication of the capillary blood flow rate.

14. A sensor device to be held against a body surface of a patient for use in investigating substances in the bloodstream, comprising a support body, a transcutaneous sensor of the thermal stimulation type on the support body for determining bloodlessly a property of a substance in a patient's blood stream, and a flow detector device for assessing bloodlessly the blood flow rate in a region of the capillary bed positioned beneath the transcutaneous 55 sensor, the flow detector device comprising radiation emitting means, including radiation directing means mounted on said support body, arranged so as, with the sensor device held against a body surface of the patient, to direct optical radiation into 60 the patient's body along a transmission path extend-

ing below said body surface, receiver means, including further radiation directing means mounted on said support body, arranged to detect optical radiation backscattered or reflected within the patient's 70 body from said transmission path along a reception path, the first and second radiation directing means being so arranged that substantially only radiation backscattered or reflected from within a region of the capillary bed below the transcutaneous sensor is 75 detected, and a processor arranged to produce an output indication of the capillary blood flow rate from the detected backscattered or reflected radiation.

15. A sensor device to be held against a body 80 surface of a patient for use in investigating substances in the bloodstream, comprising a support body, a transcutaneous sensor of the thermal stimulation type on the support body for determining bloodlessly a property of a substance in a patient's bloodstream, and a flow detector device for assessing bloodlessly the blood flow rate in a region of the capillary bed positioned beneath the transcutaneous sensor, the flow detector device comprising means on the support body for applying alternating current, 85 with the sensor device held against a body surface of the patient, between first and second space-apart points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement of the current 90 applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the patient's body 95 to be measured to provide an indication of the capillary blood flow rate.

16. A sensor device according to claim 14 or 15, further comprising means arranged to provide an indication if the blood flow rate assessed by the flow 100 detector device falls below a predetermined level.

17. A sensor device according to any one of claims 14 to 16, further comprising means arranged to prevent the effective use of the transcutaneous sensor if the blood flow rate assessed by the flow 105 detector device falls below a predetermined level.

18. A sensor according to claim 14 or 15, further comprising a visual display device arranged to provide respective displays on the same time base of the instantaneous values of said property, determined 110 by the transcutaneous sensor, and of the blood flow rate assessed by the flow detector device.

19. A sensor device according to any one of claims 14 to 18, wherein the transcutaneous sensor is a transcutaneous oxygen or CO<sub>2</sub> sensor for 115 determining the partial pressure of oxygen or CO<sub>2</sub> in the bloodstream.

20. A sensor device for use in investigating substances in the bloodstream, substantially as hereinbefore described with reference to Figure 4 or 120 5 of the accompanying drawings.